UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.*

JEREMY W. BRIGGS,
JOSEPH B. LAWRENCE, and
MARC YOUNG

BRINGING THIS ACTION ON BEHALF
OF THE UNITED STATES OF AMERICA

Plaintiffs and Relators,

v.

EXELAN PHARMACEUTICALS INC.

Defendant.

Civil Action No. 1:16-cv-1045

United States District Judge
Susan J. Dlott

SECOND AMENDED COMPLAINT

Filed under seal pursuant to
31 U.S.C. § 3730(b)(2)

DO NOT SERVE

DO NOT PUT ON PACER

Relators bring this action on behalf of the United States and on their own behalf and allege the following:

I. INTRODUCTION

1. This is a *qui tam* action brought by Relators Jeremy W. Briggs, Joseph B. Lawrence, and Marc Young **("Relators**") on behalf of the United States against Defendant Exelan Pharmaceuticals Inc. ("**Defendant Exelan**" or "**Exelan**") to recover damages and civil penalties arising from false or fraudulent statements, records, and claims made, used, or caused to be made or used by Defendant Exelan in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

2. Defendant Exelan is a privately held company located in Lawrenceville, Georgia that focuses on the sale and marketing of generic pharmaceuticals for Government and institutional markets.

3. Defendant Exelan falsely represented and/or falsely certified the country of origin for pharmaceutical products as being from Trade Agreements Act ("**TAA**") designated countries in order to obtain United States Government contracts, and knowingly sold or caused the sale of non-TAA compliant pharmaceutical products to the United States in violation of the express terms of those Government contracts. The Government contracts at issue include Contract No. VA797P-13-C-0047 (**gabapentin tablets**); Contract No. SPM2D0-14-D-N003 (**escitalopram tablets**); Contract No. SPM2D0-14-D-N010 (**alfuzosin tablets**); Contract No. SPM2D0-14-D-N005 (**finasteride tablets**); Contract No. SPE2D2-14-D-0002 (**fosinopril sodium tablets**); Contract No. VA797P-15-C-0019 (**warfarin tablets**); Contract No. SPE2D2-16-D-0032 (**sertraline HCL tablets**); Contract No. VA797P-12-C-0006 (**ramipril capsules**); Contract No.

VA797P-16-C-0057 (**naproxen**); Contract No. SPE2D2-14-D-0014 (**nabumetone**); Contract No. VA797P-15-C-0011 (**meloxicam**); Contract No. VA797P-16-C-0037 (**hydralazine HCL**); and Contract No. VA797P-17-C-0004 (**lisinopril**) (collectively referred to as "**the Government Contracts**").

4. Defendant Exelan has been perpetrating this fraud scheme since at least December 14, 2011 and continuing to the present.

5. Defendant Exelan carried out this fraudulent scheme across the United States by fraudulently bidding on and accepting orders on national Government contracts for the delivery of pharmaceutical products to pharmaceutical prime vendors for distribution to various governmental participants located throughout the United States, including medical treatment facilities, formularies, and eligible Government beneficiaries.

6. Defendant Exelan's unlawful acts in violation of the False Claims Act, as alleged herein, arise from submitting and/or causing the submission of false claims for payment to the Federal Government for pharmaceutical products, and using materially false records and statements in support of those false claims. Defendant Exelan falsely represented and/or falsely certified that its pharmaceutical products were from TAA-designated countries, failed to truthfully certify that its pharmaceutical products were from non-TAA designated countries, sold the Government pharmaceutical products that were not TAA compliant and were ineligible for payment, and knowingly submitted or caused to be submitted fraudulent information to the Government concerning the country of origin of its pharmaceutical products for the purpose of unlawfully obtaining contracts and payments that it was not entitled to receive.

II. PARTIES

7. Plaintiff in this action is the United States of America, on whose behalf Relators bring their claims.

8. Relator Jeremy W. Briggs is a pharmacist with more than 15 years of experience in the pharmaceutical industry. Relator Briggs has a Doctor of Pharmacy degree (PharmD) from the University of Kansas and an MBA from the University of Texas, San Antonio.

9. Relator Joseph B. Lawrence is a pharmacist with more than 20 years of experience in the pharmaceutical industry. Relator Lawrence has a BS in Pharmacy from Southwestern Oklahoma State University, an MBA from the University of Phoenix, and a Doctor of Pharmacy degree (PharmD) from the University of Florida, College of Pharmacy.

10. Relator Marc Young is a pharmacist with extensive project management and clinical pharmaceutical expertise. Relator Young has a Doctor of Pharmacy degree (PharmD) from Idaho State University and a Master's in Pharmacy Care Systems from Auburn University.

11. Defendant Exelan is a Delaware corporation with its principal place of business in Lawrenceville, Georgia. As noted above, Defendant Exelan is a privately held company that focuses on the sale and marketing of generic pharmaceuticals for Government and institutional markets.

12. All of the pharmaceutical products at issue in this Complaint are manufactured for Defendant Exelan by InvaGen Pharmaceuticals, Inc. ("**InvaGen**") and/or by Ascent Pharmaceuticals, Inc. ("**Ascent**"). Ascent is an affiliate of InvaGen.

13. Until February 16, 2016, both Exelan and InvaGen were wholly owned subsidiaries of Indian drugmaker Hetero Drugs Limited. Hetero Drugs Limited is based in

Hyderabad, India.

14. On or about February 16, 2016, Cipla (EU) Limited acquired Exelan and InvaGen from Hetero Drugs Limited. Cipla (EU) Limited is a wholly owned subsidiary of Indian drugmaker Cipla Limited. Cipla Limited is based in Mumbai, India.

15. After the acquisitions described in the preceding paragraph, Exelan became a wholly owned subsidiary of InvaGen and InvaGen became a wholly owned subsidiary of Cipla (EU) Limited.

III. JURISDICTION AND VENUE

16. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733. Relators bring this action pursuant to 31 U.S.C. § 3730(b)(1).

17. This Court has jurisdiction of the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345.

18. This Court has personal jurisdiction over Defendant Exelan because Exelan is a United States corporation conducting business in the United States and, pursuant to 31 U.S.C. § 3732(a), because Exelan transacts business and committed acts proscribed by 31 U.S.C. § 3729 within this judicial district.

19. Venue is likewise proper in this judicial district under 31 U.S.C. § 3732(a) because Defendant Exelan transacts business and committed acts proscribed by 31 U.S.C. § 3729 in this judicial district and in this division.

20. Personal jurisdiction and venue are proper in this district (and for venue in this division) specifically because, in violation of the express terms of its Government contracts, Defendant Exelan caused the distribution of and sought reimbursement for non-TAA compliant

pharmaceutical products distributed to the following Government entities located within this district and this division: the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505. Defendant Exelan also transacted business and committed acts proscribed by 31 U.S.C. § 3729 in this district: 1) by submitting claims for payment to the United States and receiving payment from the United States through Government pharmaceutical prime vendor Cardinal Health, Inc. ("**Cardinal Health**"), which is located in this district in Dublin, Ohio; and 2) by distributing drugs pursuant to its Government Contracts through Government pharmaceutical prime vendors including Amerisource Bergen Drug Co. which maintains a distribution center in this district in Lockbourne, Ohio.

IV. THE FALSE CLAIMS ACT

21. The False Claims Act ("**FCA**") imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. . ." 31 U.S.C. § 3729(a)(1)(A).

22. The FCA also imposes liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ." 31 U.S.C. § 3729(a)(1)(B).

23. The FCA defines "knowingly" to "mean that a person, with respect to information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the

information." 31 U.S.C. § 3729(b)(1)(A). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

24. Under the FCA, the term "claim"

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government —
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

31 U.S.C. § 3729(b)(2).

25. Prior to filing this FCA action, Relators served upon the United States a copy of their complaint and a written disclosure of substantially all material evidence and information they possessed, in accord with 31 U.S.C. § 3730(b)(2). Prior to filing the Amended Complaint, Relators served upon the United States a copy of their Amended Complaint and a written Supplemental Disclosure Statement of substantially all material evidence and information they possessed. Prior to filing this Second Amended Complaint, Relators served upon the United States a copy of their Second Amended Complaint and a written Second Supplemental Disclosure Statement of substantially all material evidence and information they possessed.

26. There has been no prior "public[] disclos[ure]," as that term is used in 31 U.S.C.

§ 3730(e)(4)(A), of the allegations and transactions on which this FCA action is based.

27. Relators are "original source[s]" of the information upon which the allegations and transactions in their complaint are based, in accord with 31 U.S.C. § 3730(e)(4)(B).

V. DEFENDANT EXELAN'S GOVERNMENT CONTRACTS REQUIRE COMPLIANCE WITH THE TRADE AGREEMENTS ACT

28. Pursuant to its Government contracts, Defendant Exelan is required to provide pharmaceutical products that are end products of a Trade Agreements Act designated country.

29. In violation of the express terms of Exelan's Government Contracts, Defendant Exelan knowingly sold or caused the sale of pharmaceutical products from non-TAA designated countries to the United States.

A. Trade Agreements Act Requirements

30. The Trade Agreements Act ("**TAA**"), 19 U.S.C. § 2501 *et seq*., requires that certain products procured by the United States Government must have specific designated countries as their country of origin.[1]

31. The TAA was enacted, in part, "to foster the growth and maintenance of an open world trading system" and "to expand opportunities for the commerce of the United States in international trade . . . ."[2]

32. The TAA applies to Government procurement contracts that equal or exceed

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[1] *See* 19 U.S.C. § 2512(a)(1)(A) (the President shall prohibit the procurement of products from non-designated foreign countries); *see also* 48 C.F.R. § 25.403(c)(1) (Under the TAA, the United States is to acquire only U.S.-made or designated country end products, for acquisitions covered by the World Trade Organization Government Procurement Agreement); 48 C.F.R. § 225.403(c)(same).

[2] 19 U.S.C. § 2502.

certain threshold amounts. *See*, *e.g.*, 48 C.F.R. § 25.1101(c)(1); 48 C.F.R. § 225.1101(6); 78 Fed. Reg. 76700 (Dec. 18, 2013).[3]

33. Only specified countries qualify as TAA-designated countries of origin for products acquired by the United States Government.[4]

34. India, China, Brazil, and Russia are among the non-permitted countries of origin under the TAA.[5]

35. For an end product that consists of materials from more than one country, that end product's country of origin is the place where the materials have been "substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed." 19 U.S.C. § 2518(4)(B); 19 C.F.R. § 177.22(a).

36. The country of origin for a pharmaceutical product is the country in which the drug's active pharmaceutical ingredient ("**API**") was sourced or produced.

37. Defendant Exelan knows, as that term is defined in the FCA, that India is the country of origin for the following pharmaceutical products it sold to the Government pursuant to contracts requiring TAA-compliant end products:

a. gabapentin tablets;

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[3] For example, for calendar years 2012 and 2013, the TAA threshold amount for applicability was $202,000.00. 76 Fed. Reg. 76808, 76809 (Dec. 8, 2011). For calendar years 2014 and 2015, the TAA threshold amount for applicability was $204,000.00. 78 Fed. Reg. 76700 (Dec. 18, 2013). For calendar years 2016 and 2017, the TAA threshold amount for applicability was $191,000.00. 80 Fed. Reg. 77,694, 77695 (Dec. 15, 2015).

[4] *See* 48 C.F.R. § 52.225-5; 48 C.F.R. § 252.225-7021.

[5] *See*, *e.g.*, 48 C.F.R. § 52.225-5.

b. escitalopram;

c. alfuzosin;

d. finasteride;

e. fosinopril sodium;

f. warfarin;

g. sertraline HCL;

h. ramipril;

i. naproxen; and

j. lisinopril.

38. Defendant Exelan knows, as that term is defined in the FCA, that the country of origin for the nabumetone, meloxicam, and hydralazine HCL that it sold to the Government (pursuant to contracts requiring TAA-compliant end products) was not a TAA-designated country.

39. As described more fully below, Defendant Exelan is knowingly selling non-TAA compliant pharmaceutical products to the United States in violation of the False Claims Act.

B. The Pharmaceutical Prime Vendor Program

40. The Pharmaceutical Prime Vendor Program ("**PPV Program**") is the contracting method used by the United States Government to distribute drugs and other pharmaceutical products to the nation's veterans and to certain other Federal Government agencies.

41. Through the PPV Program, the Department of Veterans Affairs ("**VA**") provides pharmaceutical products to various VA facilities, to the Indian Health Service ("**IHS**"), to the Bureau of Prisons ("**BoP**"), and to other governmental entities. Authorized State Veteran Homes

that have sharing agreements with VA facilities are also eligible participants in the PPV Program.

42. The Defense Logistics Agency ("**DLA**") likewise provides pharmaceutical products to the Department of Defense ("**DoD**") and to other governmental entities through the PPV Program.

43. Under the PPV Program, pharmaceutical distributors, including Defendant Exelan, enter into contracts with the VA and the DLA. These Government contracts establish a national contract price for specific pharmaceutical products to be distributed through the PPV Program.

44. Pursuant to these VA and DLA contracts, the contractor agrees to allow the designated VA and DLA/DoD Pharmaceutical Prime Vendors to deliver the specified pharmaceutical products to various governmental entities.

45. A Pharmaceutical Prime Vendor ("**PPV**") is an independent business entity that functions as the primary distributor of specified classes of products such as drugs and pharmaceuticals for purchasers like VA hospitals and DoD medical facilities.

46. Contractors, including Defendant Exelan, are required to provide the pharmaceutical products specified at the prices established in the contract to designated PPVs for distribution to DoD, VA, BoP, IHS, and to other governmental entities.

47. The PPVs place orders with the contractor for delivery to the PPVs for distribution to these various governmental participants.

48. Under the terms of a Government contract with the VA or DLA, pharmaceutical providers, including Defendant Exelan, agree to accept orders from PPVs and provide pharmaceutical products to the PPVs at the prices agreed to in the Government contract for use

by the medical treatment facilities, formularies, and eligible beneficiaries served by those PPVs.

49. Pharmaceutical providers, including Defendant Exelan, are required to report the dollar value of all sales made under a VA or DLA contract by calendar quarter. These reported sales must include all sales made, whether shipped directly to the users or through PPVs.

50. Under the terms of a VA or DLA contract, pharmaceutical providers, including Defendant Exelan, are paid for the pharmaceuticals they deliver to PPVs by those PPVs using Government funds.

51. Defendant Exelan knowingly sold non-TAA compliant pharmaceutical products to the United States through the PPV Program in violation of the False Claims Act.

52. TAA compliance is material to the Government. The Government regularly rejects bids for national contracts to supply pharmaceutical products when the TAA-compliance provision is not satisfied.

VI. EXELAN IS KNOWINGLY VIOLATING ITS GOVERNMENT CONTRACTS BY SUPPLYING NON-TAA COMPLIANT PHARMACEUTICAL PRODUCTS

53. As is described below in detail, the Government Contracts at issue in this Complaint required Exelan to supply the Government with TAA-compliant pharmaceutical products.

54. Defendant Exelan falsely certified its compliance with the Trade Agreements requirements of its Government Contracts, including on the following dates: April 19, 2012, August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017.

55. Because Exelan knowingly failed to supply TAA-compliant pharmaceutical products and because Exelan falsely certified and/or represented its compliance with the Trade

Agreements provisions in its Government Contracts, all claims for payment under the contracts identified below are false claims.

A. The Gabapentin Tablets Contract: VA Contract No. VA797P-13-C-0047

56. On April 3, 2013, the VA issued Solicitation No. VA797P-13-R-0029 seeking offers to supply its requirements of gabapentin tablets and capsules.

57. On April 30, 2013, the VA amended Solicitation No. VA797P-13-R-0029 to change the method of award to allow separate contract awards for gabapentin tablets and gabapentin capsules.

58. Gabapentin is a generic version of the brand name drug Neurontin. It is an anti-epileptic or anticonvulsant medication and is also used to treat nerve pain caused by shingles.

59. By making an offer on Solicitation No.VA797P-13-R-0029, Defendant Exelan agreed to furnish and deliver gabapentin tablets subject to the terms and conditions specified in the solicitation.

60. On June 26, 2013, Defendant Exelan was awarded Contract No. VA797P-13-C-0047 to supply gabapentin tablets to the VA pursuant to Solicitation No. VA797P-13-R-0029 (collectively the "**Gabapentin Tablets Contract**").

61. The Gabapentin Tablets Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply gabapentin tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

62. The Gabapentin Tablets Contract is for one base year, with four one-year option years.

63. The Gabapentin Tablets Contract has a contract award amount of $18,696,902.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

64. The effective date of the base year of the Gabapentin Tablets Contract was July 22, 2013.

65. On July 8, 2014, the VA exercised the first one year option available under the Gabapentin Tablets Contract, permitting governmental entities to place orders under that contract from July 22, 2014 through July 21, 2015.

66. On June 22, 2015, the VA exercised the second option year available under the Gabapentin Tablets Contract, permitting governmental entities to place orders under that contract from July 22, 2015 through July 21, 2016.

67. On July 6, 2016, the VA exercised the third option year available under the Gabapentin Tablets Contract, permitting governmental entities to place orders under that contract from July 22, 2016 through July 21, 2017.

68. On July 14, 2017, the VA exercised the fourth and final option year available under the Gabapentin Tablets Contract, permitting governmental entities to place orders under that contract from July 22, 2017 through July 21, 2018.

69. The products awarded under the Gabapentin Tablets Contract are ordered and distributed through the PPV Program.

70. The Gabapentin Tablets Contract specifies that PPVs will accept Government orders of Gabapentin Tablets and payment for such orders on behalf of Defendant Exelan.

71. The Gabapentin Tablets Contract identifies one VA PPV and five DoD PPVs.

Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

72. The governmental facilities served under the Gabapentin Tablets Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

73. The Gabapentin Tablets Contract states that, "Contracts will be awarded to the responsible offeror that submit offers meeting the solicitation requirements, and are the lowest price technically acceptable."

74. The Gabapentin Tablets Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

75. The Gabapentin Tablets Contract also provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

76. The Gabapentin Tablets Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (Nov 2012) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

77. The Gabapentin Tablets Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Gabapentin Tablets Contract also expressly

states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[6]

78. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

79. On April 19, 2012, August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

80. Specifically, on April 19, 2012, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of April 19, 2012 through September 25, 2013, certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

81. On August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

82. By submission of its offer for the Gabapentin Tablets Contract and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

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[6] No such determinations were made by the Contracting Officer.

83. However, contrary to Defendant Exelan's representations, the gabapentin tablets Defendant Exelan provides to governmental entities under Contract No. VA797P-13-C-0047 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Nov 2012).

84. The gabapentin tablets supplied by Defendant Exelan under the Gabapentin Tablets Contract are end products of India because the API in these tablets is from India.

85. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Gabapentin Tablets Contract.

86. In order to obtain the Gabapentin Tablets Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the gabapentin it was selling to the Government was a "U.S.-made or designated country end product."

87. Because the gabapentin distributed by Defendant Exelan was a product of India, it was ineligible for Government procurement under the express terms of Contract No. VA797P-13-C-0047.

88. Defendant Exelan falsely represented that the gapabentin it supplied under Contract No. VA797P-13-C-0047 was a TAA-compliant product.

89. Defendant Exelan's certifications that the gabapentin tablets supplied under Contract No. VA797P-13-C-0047 were made in the United States or in a TAA "designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

90. As specified in the Gabapentin Tablets Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Gabapentin Tablets Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for gabapentin tablets if Exelan had truthfully disclosed that the country of origin for the gabapentin tablets was India—a non-TAA country of origin.

91. All claims for payment for gabapentin tablets supplied by Defendant Exelan under Contract No. VA797P-13-C-0047 are false claims.

B. The Escitalopram Contract: DLA Contract No. SPM2D0-14-D-N003

92. On June 24, 2013, the DLA issued Solicitation No. SPM2D0-13-R-N003 seeking offers to supply its requirements of Escitalopram tablets.

93. Escitalopram is a generic version of the brand name drug Lexapro. It is an antidepressant belonging to the class of selective serotonin reuptake inhibitors (SSRIs) and is used to treat anxiety and major depressive disorder.

94. By making an offer on Solicitation No. SPM2D0-13-R-N003, Defendant Exelan agreed to furnish and deliver Escitalopram tablets subject to the terms and conditions specified in the solicitation.

95. On November 5, 2013, Defendant Exelan was awarded Contract No. SPM2D0-14-D-N003 to supply Escitalopram tablets to the DLA pursuant to Solicitation No. SPM2D0-13-R-N003 (collectively the "**Escitalopram Contract**").

96. The Escitalopram Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply Escitalopram tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

97. The Escitalopram Contract is for one base year, with four one-year option years.

98. The Escitalopram Contract has an estimated total award amount of $4,310,097.30. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

99. The effective date of the base year of the Escitalopram Contract was December 20, 2013.

100. On November 4, 2014, the DLA exercised the first option year available under the Escitalopram Contract, permitting governmental entities to continue placing orders under that contract until November 4, 2015.

101. On November 2, 2015, the DLA exercised the second option year available under the Escitalopram Contract, permitting governmental entities to continue placing orders under that contract.

102. On November 3, 2016, the DLA exercised the third option year available under the Escitalopram Contract, permitting governmental entities to continue placing orders under that contract.

103. On October 31, 2017, the DLA exercised the fourth and final option year available under the Escitalopram Contract, permitting governmental entities to continue placing orders under that contract until November 4, 2018.

104. The Escitalopram Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

105. The Escitalopram Contract requires Defendant Exelan to provide the products

specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

106. The Escitalopram Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

107. The Escitalopram Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver escitalopram tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

108. The Escitalopram Contract requires Defendant Exelan to establish a business relationship with the PPVs.

109. The Escitalopram Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

110. The governmental facilities served under the Escitalopram Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

111. The Escitalopram Contract states that "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. In order for an offer to be determined technically acceptable the proposal must receive an acceptable rating for Technical Requirements and Past Performance. . . . To receive an

acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

112. The Escitalopram Contract also states that, "For an offer to be considered technically acceptable, the offeror must comply with all terms and conditions of the Statement of Work and Solicitation."

113. The Escitalopram Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

114. The Escitalopram Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (AUG 2013) (19 U.S.C. §§ 2501-2518 and 19 U.S.C. § 3301 note).

115. The Escitalopram Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

116. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

117. The Escitalopram Contract also specifically requires Defendant Exelan to certify that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying country, or designated country end product," and to list non-compliant supplies.

118. Defendant Exelan is required to certify Trade Agreements compliance on an

annual basis.

119. On August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

120. Specifically, on August 5, 2013, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of August 5, 2013 through August 5, 2014, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country, or designated country end product.

121. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

122. By submission of its offer for the Escitalopram Contract and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

123. However, contrary to Defendant Exelan's representations, the escitalopram tablets Defendant Exelan provides to governmental entities under Contract No. SPM2D0-14-D-N003 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (AUG 2013).

124. The escitalopram tablets supplied by Defendant Exelan under the Escitalopram Contract are end products of India because the API in these tablets is from India.

125. India is not a TAA designated country of origin for the pharmaceutical products

sold to the United States Government under the Escitalopram Contract.

126. In order to obtain the Escitalopram Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the escitalopram it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

127. Because the escitalopram tablets distributed by Defendant Exelan are a product of India, they are ineligible for Government procurement under the express terms of Contract No. SPM2D0-14-D-N003.

128. Defendant Exelan falsely represented that the escitalopram it supplied under Contract No. SPM2D0-14-D-N003 was a TAA-compliant product.

129. Defendant Exelan's certifications that the escitalopram tablets supplied under Contract No. SPM2D0-14-D-N003 were made in the United States or in a TAA "qualifying or designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

130. As specified in the Escitalopram Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Escitalopram Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for escitalopram tablets if Exelan had truthfully disclosed that the country of origin for the escitalopram tablets was India—a non-TAA country of origin.

131. All claims for payment for escitalopram supplied by Defendant Exelan under Contract No. SPM2D0-14-D-N003 are false claims.

C. The Alfuzosin Contract: DLA Contract No. SPM2D0-14-D-N010

132. On November 20, 2013, the DLA issued Solicitation No. SPM2D0-13-R-N010 seeking offers to supply its requirements of alfuzosin tablets.

133. Alfuzosin is a generic version of the brand name drug Uroxatral. It is used to treat benign enlargement of the prostate (benign prostatic hyperplasia or BPH) in men.

134. By making an offer on Solicitation No. SPM2D0-13-R-N010, Defendant Exelan agreed to furnish and deliver alfuzosin tablets subject to the terms and conditions specified in the solicitation.

135. On March 18, 2014, Defendant Exelan was awarded Contract No. SPM2D0-14-D-N010 to supply alfuzosin tablets to the DLA pursuant to Solicitation No. SPM2D0-13-R-N010 (collectively the "**Alfuzosin Contract**").

136. The Alfuzosin Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply alfuzosin tablets for distribution to Government entities including the VA, DoD, IHS, and BoP.

137. The Alfuzosin Contract is for one base year, with four one-year option years.

138. The Alfuzosin Contract has an estimated total award amount of $6,898,080.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

139. The effective date of the base year of the Alfuzosin Contract was March 28, 2014.

140. On March 16, 2015, the DLA exercised the first one year option available under the Alfuzosin Contract, permitting governmental entities to continue placing orders under that contract until March 17, 2016.

141. On March 16, 2016, the DLA exercised the second one year option available under the Alfuzosin Contract, permitting governmental entities to continue placing orders under that contract.

142. On March 13, 2017, the DLA exercised the third one year option available under the Alfuzosin Contract, permitting governmental entities to continue placing orders under that contract.

143. The Alfuzosin Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

144. The Alfuzosin Contract requires Defendant Exelan to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

145. The Alfuzosin Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

146. The Alfuzosin Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver alfuzosin tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

147. The Alfuzosin Contract requires Defendant Exelan to establish a business relationship with the PPVs.

148. The Alfuzosin Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is

one of the designated DoD PPVs.

149. The governmental facilities served under the Alfuzosin Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

150. The Alfuzosin Contract states that "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. In order for an offer to be determined technically acceptable the proposal must receive an acceptable rating for Technical Requirements and Past Performance. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

151. The Alfuzosin Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

152. The Alfuzosin Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

153. The Alfuzosin Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

154. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver

"only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

155. The Alfuzosin Contract also specifically requires Defendant Exelan to certify that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying country, or designated country end product," and to list non-compliant supplies.

156. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

157. On August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

158. Specifically, on August 5, 2013, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of August 5, 2013 through August 5, 2014, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country or designated country end product.

159. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

160. By submission of its offer for the Alfuzosin Contract and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

161. However, contrary to Defendant Exelan's representations, the alfuzosin tablets

Defendant Exelan provides to governmental entities under Contract No. SPM2D0-14-D-N010 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

162. The alfuzosin tablets supplied by Defendant Exelan under the Alfuzosin Contract are end products of India because the API in these tablets is from India.

163. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Alfuzosin Contract.

164. In order to obtain the Alfuzosin Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the alfuzosin it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

165. Because the alfuzosin tablets distributed by Defendant Exelan are a product of India, they are ineligible for Government procurement under the express terms of Contract No. SPM2D0-14-D-N010.

166. Defendant Exelan falsely represented that the alfuzosin it supplied under Contract No. SPM2D0-14-D-N010 was a TAA-compliant product.

167. Defendant Exelan's certifications that the alfuzosin tablets supplied under Contract No. SPM2D0-14-D-N010 were made in the United States or in a TAA "qualifying or designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

168. As specified in the Alfuzosin Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Alfuzosin Contract, or option years

under that contract, to Exelan and Exelan would not have been paid any money for alfuzosin tablets if Exelan had truthfully disclosed that the country of origin for the alfuzosin tablets was India—a non-TAA country of origin.

169. All claims for payment for alfuzosin supplied by Defendant Exelan under Contract No. SPM2D0-14-D-N010 are false claims.

D. The Finasteride Contract: DLA Contract No. SPM2D0-14-D-N005

170. On October 29, 2013, the DLA issued Solicitation No. SPM2D0-13-R-N005 seeking offers to supply its requirements of finasteride tablets.

171. Finasteride is a generic version of the brand name drug Proscar. It is used to treat benign prostatic hyperplasia (BPH) and male pattern baldness.

172. By making an offer on Solicitation No. SPM2D0-13-R-N005, Defendant Exelan agreed to furnish and deliver finasteride tablets subject to the terms and conditions specified in the solicitation.

173. On April 9, 2014, Defendant Exelan was awarded Contract No. SPM2D0-14-D-N005 to supply finasteride tablets to the DLA pursuant to Solicitation No. SPM2D0-13-R-N005 (collectively the "**Finasteride Contract**").

174. The Finasteride Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply finasteride tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

175. The Finasteride Contract is for one base year, with four one-year option years.

176. The Finasteride Contract has an estimated total award amount of $42,546,921.00. This award amount is an estimate of the total value of all annual orders by the various

Government facilities for this drug.

177. The effective date of the base year of the Finasteride Contract was April 9, 2014.

178. On April 7, 2015, the DLA exercised the first one year option available under the Finasteride Contract, permitting governmental entities to continue placing orders under that contract until April 8, 2016.

179. On April 6, 2016, the DLA exercised the second one year option available under the Finasteride Contract, permitting governmental entities to continue placing orders under that contract.

180. On April 6, 2017, the DLA exercised the third one year option available under the Finasteride Contract, permitting governmental entities to continue placing orders under that contract.

181. The Finasteride Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

182. The Finasteride Contract requires Defendant Exelan to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

183. The Finasteride Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DoD and VA customers through the PPV.

184. The Finasteride Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver finasteride tablets to

PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

185. The Finasteride Contract requires Defendant Exelan to establish a business relationship with the PPVs.

186. The Finasteride Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

187. The governmental facilities served under the Finasteride Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

188. The Finasteride Contract states that "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. In order for an offer to be determined technically acceptable the proposal must receive an acceptable rating for Technical Requirements and Past Performance. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

189. The Finasteride Contract also states that, "For an offer to be considered technically acceptable, the offeror must comply with all terms and conditions of the Statement of Work and Solicitation."

190. The Finasteride Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In

the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

191. The Finasteride Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

192. The Finasteride Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

193. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

194. The Finasteride Contract also specifically requires Defendant Exelan to certify that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying country, or designated country end product," and to list non-compliant supplies.

195. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

196. On August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

197. Specifically, on August 5, 2013, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of August 5, 2013 through August 5, 2014, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country or designated country end product.

198. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

199. By submission of its offer for the Finasteride Contract and in its annual certifications, Defendant Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

200. However, contrary to Defendant Exelan's representations, the finasteride tablets Defendant Exelan provides to governmental entities under Contract No. SPM2D0-14-D-N005 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

201. The finasteride tablets supplied by Defendant Exelan under the Finasteride Contract are end products of India because the API in these tablets is from India.

202. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Finasteride Contract.

203. In order to obtain the Finasteride Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the finasteride it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

204. Because the finasteride tablets distributed by Defendant Exelan are a product of India, they are ineligible for Government procurement under the express terms of Contract No. SPM2D0-14-D-N005.

205. Defendant Exelan falsely represented that the finasteride it supplied under Contract No. SPM2D0-14-D-N005 was a TAA-compliant product.

206. Defendant Exelan's certifications that the finasteride tablets supplied under Contract No. SPM2D0-14-D-N005 were made in the United States or in a TAA "qualifying or designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

207. As specified in the Finasteride Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Finasteride Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for finasteride tablets if Exelan had truthfully disclosed that the country of origin for the finasteride tablets was India—a non-TAA country of origin.

208. All claims for payment for finasteride supplied by Defendant Exelan under Contract No. SPM2D0-14-D-N005 are false claims.

E. The Fosinopril Sodium Contract: DLA Contract No. SPE2D2-14-D-0002

209. On March 6, 2014, the DLA issued Solicitation No. SPM2D0-14-R-N025 seeking offers to supply its requirements of fosinopril sodium tablets.

210. On March 6, 2014, the DLA issued Amendment 0001 to Solicitation No. SPM2D0-14-R-N025, revising the schedule of supplies and providing clarifications to the original solicitation and noting that all other provisions, terms and conditions of the solicitation remained unchanged.

211. Fosinopril sodium is a generic drug that is used to treat high blood pressure and heart failure and is used to prevent kidney failure due to high blood pressure.

212. By making an offer on Solicitation No. SPM2D0-14-R-N025, Defendant Exelan agreed to furnish and deliver fosinopril sodium tablets subject to the terms and conditions specified in the solicitation.

213. On July 3, 2014, Defendant Exelan was awarded Contract No. SPE2D2-14-D-0002 to supply fosinopril sodium tablets to the DLA pursuant to Solicitation No. SPM2D0-14-R-N025 (collectively the "**Fosinopril Sodium Contract**").

214. The Fosinopril Sodium Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply fosinopril sodium tablets for distribution to federal Government entities including the VA, DoD, IHS, and BoP.

215. The Fosinopril Sodium Contract is for one base year, with four one-year option years.

216. The Fosinopril Sodium Contract has an estimated total award amount of $11,072,224.50. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

217. The effective date of the base year of the Fosinopril Contract was on or about August 21, 2014.

218. On July 2, 2015, the DLA exercised the first one year option available under the Fosinopril Sodium Contract, permitting governmental entities to continue placing orders under that contract until July 2, 2016.

219. On June 30, 2016, the DLA exercised the second one year option available under the Fosinopril Sodium Contract, permitting governmental entities to continue placing orders under that contract.

220. On June 29, 2017, the DLA exercised the third one year option available under the Fosinopril Sodium Contract, permitting governmental entities to continue placing orders under that contract.

221. The Fosinopril Sodium Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

222. The Fosinopril Sodium Contract requires Defendant Exelan to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

223. The Fosinopril Sodium Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

224. The Fosinopril Sodium Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver fosinopril sodium tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

225. The Fosinopril Sodium Contract requires Defendant Exelan to establish a business relationship with the PPVs.

226. The Fosinopril Sodium Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPvs.

227. The governmental facilities served under the Fosinopril Sodium Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical

Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

228. The Fosinopril Sodium Contract states that "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. In order for an offer to be determined technically acceptable the proposal must receive an acceptable rating for Technical Requirements and Past Performance. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

229. The Fosinopril Sodium Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

230. The Fosinopril Sodium Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (OCT 2013) (19 U.S.C. §§ 2501-2518 and 19 U.S.C. § 3301 note).

231. The Fosinopril Sodium Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

232. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

233. The Fosinopril Sodium Contract also specifically requires Defendant Exelan to certify that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying country, or designated country end product," and to list non-compliant supplies.

234. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

235. On August 5, 2013, June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

236. Specifically, on August 5, 2013, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of August 5, 2013 through August 5, 2014, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country or designated country end product.

237. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

238. By submission of its offer for the Fosinopril Sodium Contract and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

239. However, contrary to Defendant Exelan's representations, the fosinopril sodium tablets Defendant Exelan provides to governmental entities under Contract No. SPE2D2-14-D-0002 are not U.S.-made, and are not qualifying country or designated country end products under

the definitions provided in DFARS provision 252.225-7021, Trade Agreements (OCT 2013).

240. The fosinopril sodium tablets supplied by Defendant Exelan under the Fosinopril Sodium Contract are end products of India because the API in these tablets is from India.

241. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Fosinopril Sodium Contract.

242. In order to obtain the Fosinopril Sodium Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the fosinopril sodium it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

243. Because the fosinopril sodium distributed by Defendant Exelan is a product of India, it is ineligible for Government procurement under the express terms of Contract No. SPE2D2-14-D-0002.

244. Defendant Exelan falsely represented that the fosinopril sodium it supplied under Contract No. SPE2D2-14-D-0002 was a TAA-compliant product.

245. Defendant Exelan's certifications that the fosinopril sodium tablets supplied under Contract No. SPE2D2-14-D-0002 were made in the United States or in a TAA "qualifying or designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

246. As specified in the Fosinopril Sodium Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Fosinopril Sodium Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for fosinopril sodium tablets if Exelan had truthfully disclosed that the country of origin

for the fosinopril sodium tablets was India—a non-TAA country of origin.

247. All claims for payment for fosinopril sodium supplied by Defendant Exelan under Contract No. SPE2D2-14-D-0002 are false claims.

F. The Warfarin Contract: VA Contract No. VA797P-15-C-0019

248. On December 31, 2014, the VA issued Solicitation No. VA797P-15-R-0043 seeking offers to supply its requirements of warfarin tablets.

249. On January 14, 2015, the VA amended its solicitation to correct line item 5 to read "Warfarin NA 2.5MG 1000s."

250. Warfarin is a generic version of the brand name drugs Coumadin and Jantoven. It is an anticoagulant (blood thinner) used to treat or prevent blood clots in veins or arteries. It can reduce the risk of stroke and heart attack.

251. By making an offer on Solicitation No.VA797P-15-R-0043, Defendant Exelan agreed to furnish and deliver warfarin tablets subject to the terms and conditions specified in the solicitation.

252. On March 2, 2015, Defendant Exelan was awarded Contract No. VA797P-15-C-0019 to supply warfarin tablets to the VA pursuant to Solicitation No. VA797P-15-R-0043 (collectively the "**Warfarin Contract**").

253. The Warfarin Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply warfarin tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

254. The Warfarin Contract is for one base year, with four one-year option years.

255. The Warfarin Contract has a contract award amount of $29,201,731.00. This

award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

256. The effective date of the base year of the Warfarin Contract was April 6, 2015.

257. On March 25, 2016, the VA exercised the first one year option available under the Warfarin Contract, permitting governmental entities to place orders under that contract from April 6, 2016 through April 5, 2017.

258. On March 22, 2017, the VA exercised the second one year option available under the Warfarin Contract, permitting governmental entities to place orders under that contract from April 6, 2017 through April 5, 2018.

259. The products awarded under the Warfarin Contract are ordered and distributed through the PPV Program.

260. The Warfarin Contract specifies that PPVs will accept Government orders for warfarin tablets and payment for such orders on behalf of Defendant Exelan.

261. The Warfarin Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

262. The governmental facilities served under the Warfarin Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

263. The Warfarin Contract provides that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest

price technically acceptable offer."

264. The Warfarin Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

265. The Warfarin Contract states that all delivery orders under that contract "are subject to the terms and conditions of this contract."

266. The Warfarin Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

267. The Warfarin Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Warfarin Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[7]

268. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

269. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's

[7] No such determinations were made by the Contracting Officer.

certification of Trade Agreements compliance and made these annual certifications.

270. Specifically, on June 20, 2014, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of June 20, 2014 through June 20, 2015, certifying on behalf of Exelan that each end product is a U.S.-made, designated country end product.

271. On May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

272. By submission of its offer for the Warfarin Contract, and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

273. However, contrary to Defendant Exelan's representations, the warfarin tablets Defendant Exelan provides to governmental entities under Contract No. VA797P-15-C-0019 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

274. The warfarin tablets supplied by Defendant Exelan under the Warfarin Contract are end products of India because the API in these tablets is from India.

275. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Warfarin Contract.

276. In order to obtain the Warfarin Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the

warfarin it was selling to the Government was a "U.S.-made, designated country end product."

277. Because the warfarin distributed by Defendant Exelan was a product of India, it was ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0019.

278. Defendant Exelan falsely represented that the warfarin it supplied under Contract No. VA797P-15-C-0019 was a TAA-compliant product.

279. Defendant Exelan's certifications that the warfarin tablets supplied under Contract No. VA797P-15-C-0019 were made in the United States or in a TAA "designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

280. As specified in the Warfarin Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Warfarin Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for warfarin tablets if Exelan had truthfully disclosed that the country of origin for the warfarin tablets was India—a non-TAA country of origin.

281. All claims for payment for warfarin supplied by Defendant Exelan under Contract No. VA797P-15-C-0019 are false claims.

G. The Sertraline HCL Contract: DLA Contract No. SPE2D2-16-D-0032

282. On August 25, 2015, the DLA issued Solicitation No. SPE2D2-15-R-0014 seeking offers to supply its requirements of sertraline HCL tablets.

283. On August 25, 2015, the DLA issued two amendments to Solicitation No. SPE2D2-15-R-0014, updating the schedule of supplies and the purchase compliance paragraph

of the Statement of Work.

284. Sertraline HCL is a generic version of the brand name drug Zoloft. It is an antidepressant in a group of drugs called selective serotonin reuptake inhibitors (SSRIs) and is used to treat depression, obsessive-compulsive disorder, panic disorder, anxiety disorders, post-traumatic stress disorder (PTSD), and premenstrual dysphoric disorder (PMDD).

285. By making an offer on Solicitation No. SPE2D2-15-R-0014, Defendant Exelan agreed to furnish and deliver sertraline HCL tablets subject to the terms and conditions specified in the solicitation.

286. On January 19, 2016, Defendant Exelan was awarded Contract No. SPE2D2-16-D-0032 to supply sertraline HCL tablets to the DLA pursuant to Solicitation No. SPE2D2-15-R-0014 (collectively the "**Sertraline HCL Contract**").

287. The Sertraline HCL Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply sertraline HCL tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

288. The Sertraline HCL Contract is for one base year, with four one-year option years.

289. The Sertraline HCL Contract has an estimated total award amount of $32,024,382.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

290. The effective date of the base year of the Sertraline HCL Contract was January 19, 2016.

291. On January 12, 2017, the DLA exercised the first one year option available under the Sertraline HCL Contract, permitting governmental entities to continue placing orders under

that contract.

292. The Sertraline HCL Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DLA prime vendors to distribute the listed products at the prices established in that contract.

293. The Sertraline HCL Contract requires Defendant Exelan to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

294. The Sertraline HCL Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

295. The Sertraline HCL Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver sertraline HCL tablets to PPVs for distribution to DLA and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

296. The Sertraline HCL Contract requires Defendant Exelan to establish a business relationship with the PPVs.

297. The Sertraline HCL Contract identifies five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPvs.

298. The governmental facilities served under the Sertraline HCL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512

South Burnett Road, Springfield, Ohio 45505.

299. The Sertraline HCL Contract states that "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated aggregate price. In order for an offer to be determined technically acceptable the proposal must receive an acceptable rating for Technical Requirements and Past Performance. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

300. The Sertraline HCL Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

301. The Sertraline HCL Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (NOV 2014) (19 U.S.C. §§ 2501-2518 and § 19 U.S.C. 3301 note).

302. The Sertraline HCL Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

303. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

304. The Sertraline HCL Contract also specifically requires Defendant Exelan to certify that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying

country, or designated country end product," and to list the Country of Origin of non-compliant end products.

305. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

306. On May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

307. Specifically, on May 8, 2015, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of May 8, 2015 through May 7, 2016, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country or designated country end product.

308. On April 26, 2016, and on March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time period beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

309. By submission of its offer for the Sertraline HCL Contract and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

310. However, contrary to Defendant Exelan's representations, the sertraline HCL tablets Defendant Exelan provides to governmental entities under Contract No. SPE2D2-16-D-0032 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (NOV 2014).

311. The sertraline HCL tablets supplied by Defendant Exelan under the Sertraline HCL Contract are end products of India because the API in these tablets is from India.

312. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Sertraline HCL Contract.

313. In order to obtain the Sertraline HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the sertraline HCL it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

314. Because the sertraline HCL tablets distributed by Defendant Exelan are a product of India, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-16-D-0032.

315. Defendant Exelan falsely represented that the sertraline HCL it supplied under Contract No. SPE2D2-16-D-0032 was a TAA-compliant product.

316. Defendant Exelan's certifications that the sertraline HCL tablets supplied under Contract No. SPE2D2-16-D-0032 are made in the United States or in a TAA "qualifying or designated country" are false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

317. As specified in the Sertraline HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Sertraline HCL Contract to Exelan and Exelan would not have been paid any money for sertraline HCL tablets if Exelan had truthfully disclosed that the country of origin for the sertraline HCL tablets was India—a non-TAA country of origin.

318. All claims for payment for sertraline HCL supplied by Defendant Exelan under Contract No. SPE2D2-16-D-0032 are false claims.

H. The Ramipril Contract: VA Contract No. VA797P-12-C-0006

319. On July 11, 2011, the VA issued Solicitation No. VA797-11-RP-0115 seeking offers to supply its requirements of ramipril capsules.

320. Ramipril is a generic version of the brand name drug Altace. It is used to treat high blood pressure (hypertension) or congestive heart failure, and to improve survival after a heart attack.

321. By making an offer on Solicitation No. VA797-11-RP-0115, Defendant Exelan agreed to furnish and deliver ramipril capsules subject to the terms and conditions specified in the solicitation.

322. On December 14, 2011, Defendant Exelan was awarded Contract No. VA797P-12-C-0006 to supply ramipril capsules to the VA pursuant to Solicitation No. VA797-11-RP-0015 (collectively the "**Ramipril Contract**").

323. The Ramipril Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply ramipril capsules for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

324. The Ramipril Contract is for one base year, with four one-year option years.

325. The Ramipril Contract has a contract award amount of $1,917,306.79. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

326. The effective date of the base year of the Ramipril Contract was January 19, 2012.

327. On December 4, 2012, the VA exercised the first one year option available under the Ramipril Contract, permitting governmental entities to place orders under that contract from January 19, 2013 through January 18, 2014.

328. On or about December 18, 2013, the VA exercised the second option year available under the Ramipril Contract, permitting governmental entities to continue placing orders under that contract.

329. On December 22, 2014, the VA exercised the third option year available under the Ramipril Contract, permitting governmental entities to place orders under that contract from January 19, 2015 through January 18, 2016.

330. On December 22, 2015, the VA exercised the fourth and final option year available under the Ramipril Contract, permitting governmental entities to place orders under that contract from January 19, 2016 through January 18, 2017.

331. The products awarded under the Ramipril Contract are ordered and distributed through the PPV Program.

332. Pursuant to the PPV Program, PPVs accept Government orders of ramipril capsules and payment for such orders on behalf of Defendant Exelan.

333. The governmental facilities served under the Ramipril Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

334. Pursuant to federal law, Defendant Exelan is required to comply with FAR

provision 52.225-5, Trade Agreements, while performing the Ramipril Contract. *See* 48 C.F.R. § 25.1101(c)(1); 48 C.F.R. § 52.225–5.

335. Federal law also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products or supplies. 48 C.F.R. § 25.1101(c)(2); 48 C.F.R.§ 52.225–6.

336. The Government is to "consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation." 48 C.F.R. § 52.225–6(c).

337. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis. *See* 48 C.F.R. § 52.212–3.

338. On April 19, 2012, August 5, 2013, June 20, 2014, May 8, 2015, and April 26, 2016, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made these annual certifications.

339. Specifically, on April 19, 2012, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of April 19, 2012 through September 25, 2013, certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

340. On August 5, 2013, June 20, 2014, May 8, 2015, and April 26, 2016, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of

Exelan's certification of Trade Agreements compliance.

341. By submission of its offer for the Ramipril Contract, and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

342. However, contrary to Defendant Exelan's representations, the ramipril capsules Defendant Exelan provides to governmental entities under Contract No. VA797P-12-C-0006 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements.

343. The ramipril capsules supplied by Defendant Exelan under the Ramipril Contract are end products of India because the API in these capsules is from India.

344. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Ramipril Contract.

345. In order to obtain the Ramipril Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the ramipril it was selling to the Government was a "U.S.-made or designated country end product."

346. Because the ramipril distributed by Defendant Exelan was a product of India, it was ineligible for Government procurement under Contract No. VA797P-12-C-0006.

347. Defendant Exelan falsely represented that the ramipril it supplied under Contract No. VA797P-12-C-0006 was a TAA-compliant product.

348. Defendant Exelan's certifications that the ramipril capsules supplied under Contract No. VA797P-12-C-0006 were made in the United States or in a TAA "designated country" were false. Exelan made these false certifications "knowingly," as that term is defined

in 31 U.S.C § 3729(b)(1).

349. As required by federal law and as reiterated in the Trade Agreements Certificate, the Government would not have awarded the Ramipril Contract, or option years under that contract, to Exelan and Exelan would not have been paid any money for ramipril capsules if Exelan had truthfully disclosed that the country of origin for the ramipril capsules was India—a non-TAA country of origin.

350. All claims for payment for ramipril supplied by Defendant Exelan under Contract No. VA797P-12-C-0006 are false claims.

I. The Naproxen Contract: VA Contract No. VA797P-16-C-0057

351. On December 14, 2015, the VA issued Solicitation No. VA797P-16-R-0021 seeking offers to supply its requirements of naproxen tablets.

352. Naproxen is a generic version of the brand name drugs Aleve, Anaprox, EC-Naprosyn, and Flanax. It is a nonsteroidal anti-inflammatory drug used to treat pain or inflammation caused by arthritis, ankylosing spondylitis, tendinitis, bursitis, gout, or menstrual cramps.

353. By making an offer on Solicitation No.VA797P-16-R-0021, Defendant Exelan agreed to furnish and deliver naproxen tablets subject to the terms and conditions specified in the solicitation.

354. On June 1, 2016, Defendant Exelan was awarded Contract No. VA797P-16-C-0057 to supply naproxen tablets to the VA pursuant to Solicitation No. VA797P-16-R-0021 (collectively the "**Naproxen Contract**").

355. The Naproxen Contract is a firm fixed price requirements contract whereby

Defendant Exelan agreed to supply naproxen tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

356. The Naproxen Contract is for one base year, with four one-year option years.

357. The Naproxen Contract has a contract award amount of $23,659,702.00. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

358. The effective date of the base year of the Naproxen Contract was August 1, 2016.

359. On July 20, 2017, the VA exercised the first option year available under the Naproxen Contract, permitting governmental entities to place orders under that contract from August 1, 2017 through July 31, 2018.

360. The products awarded under the Naproxen Contract are ordered and distributed through the PPV Program.

361. The Naproxen Contract specifies that PPVs will accept Government orders for naproxen tablets and payment for such orders on behalf of Defendant Exelan.

362. The Naproxen Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

363. The governmental facilities served under the Naproxen Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

364. The Naproxen Contract provides that, “A contract will be awarded to the

responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

365. The Naproxen Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

366. The Naproxen Contract states that all delivery orders under that contract "are subject to the terms and conditions of this contract."

367. The Naproxen Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

368. The Naproxen Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Naproxen Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[8]

369. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

370. On April 26, 2016, and on March 3, 2017, Kathleen Ramos, Manager Contracts

[8] No such determinations were made by the Contracting Officer.

and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made this annual certification.

371. Specifically, on April 26, 2016, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of April 26, 2016 through April 26, 2017, certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

372. On March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the one year time period beginning on that date, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

373. By submission of its offer for the Naproxen Contract, and in its annual certifications, Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

374. However, contrary to Defendant Exelan's representations, the naproxen tablets Defendant Exelan provides to governmental entities under Contract No. VA797P-16-C-0057 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Nov 2013).

375. The naproxen tablets supplied by Defendant Exelan under the Naproxen Contract are end products of India because the API in these tablets is from India.

376. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Naproxen Contract.

377. In order to obtain the Naproxen Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the

naproxen it was selling to the Government was a "U.S.-made or designated country end product."

378. Because the naproxen distributed by Defendant Exelan was a product of India, it was ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0057.

379. Defendant Exelan falsely represented that the naproxen it supplied under Contract No. VA797P-16-C-0057 was a TAA-compliant product.

380. Defendant Exelan's certifications that the naproxen tablets supplied under Contract No. VA797P-16-C-0057 were made in the United States or in a TAA "designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

381. As specified in the Naproxen Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Naproxen Contract to Exelan and Exelan would not have been paid any money for naproxen tablets if Exelan had truthfully disclosed that the country of origin for the naproxen tablets was India—a non-TAA country of origin.

382. All claims for payment for naproxen tablets supplied by Defendant Exelan under Contract No. VA797P-16-C-0057 are false claims.

J. The Nabumetone Contract: DLA Contract No. SPE2D2-14-D-0014

383. On March 27, 2014, the DLA issued Solicitation No. SPM2D0-14-R-N022 seeking offers to supply its requirements of nabumetone tablets.

384. On April 3, 2014, Solicitation No. SPM2D0-14-R-N022 was modified to update the Schedule of Supplies.

385. Nabumetone is a generic version of the brand name drug Relafen. It is a non-steroidal anti-inflammatory drug (NSAID) used to relieve the symptoms of rheumatoid arthritis or osteoarthritis.

386. By making an offer on Solicitation No. SPM2D0-14-R-N022, Defendant Exelan agreed to furnish and deliver nabumetone tablets subject to the terms and conditions specified in the solicitation.

387. On September 8, 2014, Defendant Exelan was awarded Contract No. SPE2D2-14-D-0014 to supply nabumetone tablets to the DLA pursuant to Solicitation No. SPM2D0-14-R-N022 (collectively the "**Nabumetone Contract**").

388. The Nabumetone Contract is a requirements contract whereby Defendant Exelan agreed to supply nabumetone tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

389. The Nabumetone Contract is for one base year, with four one-year option years.

390. The Nabumetone Contract has an estimated total award amount of $2,515,250.00. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

391. The effective date of the base year of the Nabumetone Contract was September 8, 2014.

392. On September 1, 2015, the DLA exercised the first one year option available under the Nabumetone Contract, permitting governmental entities to continue placing orders under that contract.

393. On September 1, 2016, the DLA exercised the second option year available under

the Nabumetone Contract, permitting governmental entities to continue placing orders under that contract.

394. On August 23, 2017, the DLA exercised the third option year available under the Nabumetone Contract, permitting governmental entities to continue placing orders under that contract.

395. The Nabumetone Contract specifies that Defendant Exelan, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

396. The Nabumetone Contract requires Defendant Exelan to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

397. The Nabumetone Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

398. The Nabumetone Contract requires Defendant Exelan to accept orders from designated PPVs at the prices agreed to under the contract and to deliver nabumetone tablets to PPVs for distribution to DLA and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

399. The Nabumetone Contract requires Defendant Exelan to establish a business relationship with the PPVs.

400. The Nabumetone Contract identifies five PPVs, including Cardinal Health of Dublin, Ohio.

401. The governmental facilities served under the Nabumetone Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

402. The Nabumetone Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

403. The Nabumetone Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

404. The Nabumetone Contract specifically requires Defendant Exelan to comply with DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

405. The Nabumetone Contract also specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

406. DFARS 252.225-7021, Trade Agreements, requires Defendant Exelan to deliver "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225–7021(c) (DFARS 252.225-7021(c)).

407. The Nabumetone Contract also specifically requires Defendant Exelan to certify

that "each end product to be delivered under this contract . . . is a U.S.-made, qualifying country, or designated country end product," and to list non-compliant supplies.

408. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

409. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made this annual certification.

410. Specifically, on June 20, 2014, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of June 20, 2014 through June 20, 2015, certifying on behalf of Exelan that each end product is a U.S.-made, qualifying country, or designated country end product.

411. On May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

412. By submission of its offer for the Nabumetone Contract and in its annual certifications, Exelan affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

413. However, contrary to Defendant Exelan's representations, the nabumetone tablets Defendant Exelan provides to governmental entities under Contract No. SPE2D2-14-D-0014 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

414. The nabumetone tablets supplied by Defendant Exelan under the Nabumetone Contract are end products of a non-TAA designated country of origin.

415. In order to obtain the Nabumetone Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the nabumetone it was selling to the Government was a "U.S.-made, qualifying country, or designated country end product."

416. Because the nabumetone tablets distributed by Defendant Exelan are not a product of a TAA designated country, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-14-D-0014.

417. Defendant Exelan falsely represented that the nabumetone it supplied under Contract No. SPE2D2-14-D-0014 was a TAA-compliant product.

418. Defendant Exelan's certifications that the nabumetone tablets supplied under Contract No. SPE2D2-14-D-0014 were made in the United States or in a TAA qualifying or designated country were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

419. As specified in the Nabumetone Contract, the Government would not have awarded the Nabumetone Contract, or option years under that contract, to Defendant Exelan and Exelan would not have been paid any money for nabumetone tablets if Exelan had truthfully disclosed in its bid that the country of origin for the nabumetone tablets was a non-TAA country of origin.

420. All claims for payment for nabumetone tablets supplied by Defendant Exelan under Contract No. SPE2D2-14-D-0014 are false claims.

K. The Meloxicam Contract: VA Contract No. VA797P-15-C-0011

421. On October 30, 2014, the VA issued Solicitation No. VA797P-14-R-0065 seeking offers to supply its requirements of meloxicam tablets.

422. Meloxicam is a generic version of the brand name drugs Moblic and Vivlodex. It is a nonsteroidal anti-inflammatory drug (NSAID) used to treat pain or inflammation caused by rheumatoid arthritis and osteoarthritis in adults. It is also used to treat juvenile rheumatoid arthritis in children who are at least two years old.

423. By making an offer on Solicitation No.VA797P-14-R-0065, Defendant Exelan agreed to furnish and deliver meloxicam tablets subject to the terms and conditions specified in the solicitation.

424. On January 5, 2015, Defendant Exelan was awarded Contract No. VA797P-15-C-0011 to supply meloxicam tablets to the VA pursuant to Solicitation No. VA797P-14-R-0065 (collectively the "**Meloxicam Contract**").

425. The Meloxicam Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply meloxicam tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

426. The Meloxicam Contract is for one base year, with four one-year option years.

427. The Meloxicam Contract has a contract award amount of $10,718,697.75. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

428. The effective date of the base year of the Meloxicam Contract was February 24, 2015.

429. On January 25, 2016, the VA exercised the first one year option available under the Meloxicam Contract, permitting governmental entities to place orders under that contract from February 24, 2016 until February 23, 2017.

430. On January 11, 2017, the VA exercised the second one year option available under the Meloxicam Contract, permitting governmental entities to place orders under that contract from January 24, 2017 until February 23, 2018.

431. On January 23, 2018, the VA exercised the third one year option available under the Meloxicam Contract, permitting governmental entities to place orders under that contract from February 24, 2018 until February 23, 2019.

432. The products awarded under the Meloxicam Contract are ordered and distributed through the PPV Program.

433. The Meloxicam Contract specifies that PPVs will accept Government orders for meloxicam tablets and payment for such orders on behalf of Defendant Exelan.

434. The Meloxicam Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

435. The governmental facilities served under the Meloxicam Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

436. The Meloxicam Contract provides that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest

price technically acceptable offer."

437. The Meloxicam Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

438. The Meloxicam Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

439. The Meloxicam Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

440. The Meloxicam Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Meloxicam Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[9]

441. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

442. On June 20, 2014, May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's

[9] No such determinations were made by the Contracting Officer.

certification of Trade Agreements compliance and made this annual certification.

443. Specifically, on June 20, 2014, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of June 20, 2014 through June 20, 2015, certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

444. On May 8, 2015, April 26, 2016, and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

445. By submission of its offer for the Meloxicam Contract, and in its annual certifications, Defendant Exelan verified that its Trade Agreements certifications were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

446. However, contrary to Defendant Exelan's representations, the meloxicam tablets Defendant Exelan provides to governmental entities under Contract No. VA797P-15-C-0011 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Nov 2013).

447. The meloxicam tablets supplied by Defendant Exelan under the Meloxicam Contract are end products of a non-TAA designated country of origin.

448. In order to obtain the Meloxicam Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the meloxicam it was selling to the Government was a "U.S.-made or designated country end product."

449. Because the meloxicam tablets distributed by Defendant Exelan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0011.

450. Defendant Exelan falsely represented that the meloxicam it supplied under Contract No. VA797P-15-C-0011 was a TAA-compliant product.

451. Defendant Exelan's certifications that the meloxicam tablets supplied under Contract No. VA797P-15-C-0011 were made in the United States or in a TAA "designated country" were false. Defendant Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

452. As specified in the Meloxicam Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Meloxicam Contract, or option years under that contract, to Defendant Exelan and Exelan would not have been paid any money for meloxicam tablets if Exelan had truthfully disclosed in its bid that the country of origin for the meloxicam tablets was a non-TAA country of origin.

453. All claims for payment for the meloxicam tablets supplied by Defendant Exelan under Contract No. VA797P-15-C-0011 are false claims.

L. The Hydralazine HCL Contract: VA Contract No. VA797P-16-C-0037

454. On October 26, 2015, the VA issued Solicitation No. VA797P-15-R-0086 seeking offers to supply its requirements of hydralazine HCL tablets.

455. Hydralazine HCL is a generic version of the brand name drug Apresoline. It is a vasodilator that is used to treat hypertension (high blood pressure).

456. By making an offer on Solicitation No.VA797P-15-R-0086, Defendant Exelan

agreed to furnish and deliver hydralazine HCL tablets subject to the terms and conditions specified in the solicitation.

457. On February 9, 2016, Defendant Exelan was awarded Contract No. VA797P-16-C-0037 to supply hydralazine HCL tablets to the VA pursuant to Solicitation No. VA797P-15-R-0086 (collectively the "**Hydralazine HCL Contract**").

458. The Hydralazine HCL Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply hydralazine HCL tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

459. The Hydralazine HCL Contract is for one base year, with four one-year option years.

460. The Hydralazine HCL Contract has a contract award amount of $15,262,345.00. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

461. The effective date of the base year of the Hydralazine HCL Contract was April 8, 2016.

462. On March 20, 2017, the VA exercised the first one year option available under the Hydralazine HCL Contract, permitting governmental entities to place orders under that contract from April 8, 2017 until April 7, 2018.

463. The products awarded under the Hydralazine HCL Contract are ordered and distributed through the PPV Program.

464. The Hydralazine HCL Contract specifies that PPVs will accept Government

orders for hydralazine HCL tablets and payment for such orders on behalf of Defendant Exelan.

465. The Hydralazine HCL Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

466. The governmental facilities served under the Hydralazine HCL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

467. The Hydralazine HCL Contract provides that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

468. The Hydralazine HCL Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

469. The Hydralazine HCL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

470. The Hydralazine HCL Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

471. The Hydralazine HCL Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in

the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Hydralazine HCL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[10]

472. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

473. On May 8, 2015, April 26, 2016, and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made this annual certification.

474. Specifically, on May 8, 2015, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of May 8, 2015 through May 8, 2016, certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

475. On April 26, 2016 and March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the respective one year time periods beginning on each of those dates, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

476. By submission of its offer for the Hydralazine HCL Contract, and in its annual certifications, Defendant Exelan verified that its Trade Agreements certifications were current,

[10] No such determinations were made by the Contracting Officer.

accurate, complete, applicable to this solicitation, and incorporated by reference.

477. However, contrary to Defendant Exelan's representations, the hydralazine HCL tablets Defendant Exelan provides to governmental entities under Contract No. VA797P-16-C-0037 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Nov 2013).

478. The hydralazine HCL tablets supplied by Defendant Exelan under the Hydralazine HCL Contract are end products of non-TAA designated country of origin.

479. In order to obtain the Hydralazine HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Exelan falsely certified that the Hydralazine HCL it was selling to the Government was a "U.S.-made or designated country end product."

480. Because the hydralazine HCL tablets distributed by Defendant Exelan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0037.

481. Defendant Exelan falsely represented that the hydralazine HCL it supplied under Contract No. VA797P-16-C-0037 was a TAA-compliant product.

482. Defendant Exelan's certifications that the hydralazine HCL tablets supplied under Contract No. VA797P-16-C-0037 were made in the United States or in a TAA "designated country" were false. Defendant Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

483. As specified in the Hydralazine HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Hydralazine HCL Contract,

or option years under that contract, to Defendant Exelan and Exelan would not have been paid any money for hydralazine HCL tablets if Exelan had truthfully disclosed that the country of origin for the hydralazine HCL tablets was a non-TAA country of origin.

484. All claims for payment for the hydralazine HCL tablets supplied by Defendant Exelan under Contract No. VA797P-16-C-0037 are false claims.

M. The Lisinopril Contract: VA Contract No. VA797P-17-C-0004

485. On September 14, 2016, the VA issued Solicitation No. VA797P-16-R-0093 seeking offers to supply its requirements of lisinopril tablets.

486. Lisinopril is a generic version of the brand name drugs Prinivil, Qbrelis, and Zestril. It is an ACE (angiotensin converting enzyme) inhibitor used to treat hypertension in adults and children who are at least six years old. It is also used to treat congestive heart failure in adults, or to improve survival after a heart attack.

487. By making an offer on Solicitation No.VA797P-16-R-0093, Defendant Exelan agreed to furnish and deliver lisinopril tablets subject to the terms and conditions specified in the solicitation.

488. On November 22, 2016, Defendant Exelan was awarded Contract No. VA797P-17-C-0004 to supply lisinopril tablets to the VA pursuant to Solicitation No. VA797P-16-R-0093 (collectively the "**Lisinopril Contract**").

489. The Lisinopril Contract is a firm fixed price requirements contract whereby Defendant Exelan agreed to supply lisinopril tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

490. The Lisinopril Contract is for one base year, with four one-year option years.

491. The Lisinopril Contract has a contract award amount of $52,443,105.05. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

492. The effective date of the base year of the Lisinopril Contract was January 6, 2017.

493. On January 2, 2018, the VA opted to not exercise the first option year, instead allowing the Lisinopril Contract to expire on January 5, 2018.

494. The products awarded under the Lisinopril Contract are ordered and distributed through the PPV Program.

495. The Lisinopril Contract specifies that PPVs will accept Government orders for lisinopril tablets and payment for such orders on behalf of Defendant Exelan.

496. The Lisinopril Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

497. The governmental facilities served under the Lisinopril Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

498. The Lisinopril Contract provides that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

499. The Lisinopril Contract also provides that the Government may terminate the contract for cause if Defendant Exelan fails to comply with any contract terms and conditions. In

the event of such a termination for cause, Defendant Exelan shall be liable to the Government for any and all rights and remedies provided by law.

500. The Lisinopril Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

501. The Lisinopril Contract specifically requires Defendant Exelan to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

502. The Lisinopril Contract also specifically requires Defendant Exelan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list the Country of Origin of non-compliant end products. This provision of the Lisinopril Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[11]

503. Defendant Exelan is required to certify Trade Agreements compliance on an annual basis.

504. On April 26, 2016 and March 3, 2017, Kathleen Ramos, Manager Contracts and Pricing for Exelan, attested to the accuracy of Exelan's certification of Trade Agreements compliance and made this annual certification.

505. Specifically, on April 26, 2016, Ms. Ramos executed the Trade Agreements certification for Defendant Exelan for the time period of April 26, 2016 through April 26, 2017,

[11] No such determinations were made by the Contracting Officer.

certifying on behalf of Exelan that each end product is a U.S.-made or designated country end product.

506. On March 3, 2017, Ms. Ramos again executed this same Trade Agreements Certificate for Defendant Exelan for the one year time period ending March 3, 2018, again attesting to the accuracy of Exelan's certification of Trade Agreements compliance.

507. By submission of its offer for the Lisinopril Contract, and in its annual certifications, Defendant Exelan verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

508. However, contrary to Defendant Exelan's representations, the lisinopril tablets Defendant Exelan provided to governmental entities under Contract No. VA797P-17-C-0004 were not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

509. The lisinopril tablets supplied by Defendant Exelan under the Lisinopril Contract are end products of India because the API in these tablets is from India.

510. India is not a TAA designated country of origin for the pharmaceutical products sold to the United States Government under the Lisinopril Contract.

511. In order to obtain the Lisinopril Contract and payments pursuant to that contract, Defendant Exelan falsely certified that the lisinopril it was selling to the Government was a "U.S.-made or designated country end product."

512. Because the lisinopril distributed by Defendant Exelan was a product of India, it was ineligible for Government procurement under the express terms of Contract No. VA797P-17-C-0004.

513. Defendant Exelan falsely represented that the lisinopril it supplied under Contract No. VA797P-17-C-0004 was a TAA-compliant product.

514. Defendant Exelan's certifications that the lisinopril tablets supplied under Contract No. VA797P-17-C-0004 were made in the United States or in a TAA "designated country" were false. Exelan made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

515. As specified in the Lisinopril Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Lisinopril Contract to Defendant Exelan and Exelan would not have been paid any money for lisinopril tablets if Exelan had truthfully disclosed in its bid that the country of origin for the lisinopril tablets was India—a non-TAA country of origin.

516. All claims for payment for the lisinopril supplied by Defendant Exelan under Contract No. VA797P-17-C-0004 are false claims.

COUNT I-VIOLATION OF 31 U.S.C. § 3729(A)(1)(A)

517. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

518. Defendant Exelan, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

519. By virtue of the conduct described above, Defendant Exelan knowingly presented or caused to be presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(A).

520. Defendant Exelan "knowingly" violated the False Claims Act, as that term is

defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant Exelan acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

521. As a result of Defendant Exelan's violations of 31 U.S.C. § 3729(a)(1)(A), the Government has suffered actual damages in an amount to be determined at trial.

COUNT II-VIOLATION OF 31 U.S.C. § 3729(A)(1)(B)

522. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

523. Defendant Exelan, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

524. By virtue of the conduct described above, Defendant Exelan knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

525. Defendant Exelan "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant Exelan acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

526. As a result of Defendant Exelan's violations of 31 U.S.C. § 3729(a)(1)(B), the Government has suffered actual damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE Relators, on behalf of themselves and the United States, pray for judgment against Defendant Exelan as follows:

A. That this Court enter judgment against Defendant Exelan in an amount equal to three times the amount of damages sustained by the United States because of Defendant Exelan's acts in violation of the False Claims Act, plus the maximum civil penalty for each violation of the False Claims Act, as provided by 31 U.S.C. § 3729(a)(1);

B. That Relators be awarded all reasonable expenses incurred, plus reasonable attorneys' fees and costs, in accord with 31 U.S.C. § 3730(d);

C. That, in the event the United States intervenes, that Relators be awarded 25% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(1);

D. That, in the event the United States does not intervene, that Relators be awarded 30% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(2);

E. That Relators be awarded a share of any alternate remedy that the United States elects to pursue;

F. That Defendant Exelan, its subsidiaries, affiliates, and related organizations be found to have violated the False Claims Act and be enjoined from future violations of that act;

G. That the United States and Relators be awarded pre-judgment and post-judgment interest; and

H. That the United States and Relators receive all relief, both at law and in equity to which they may be reasonably entitled.

Respectfully submitted,

Date: February 23, 2018

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Attorneys for Relators

CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2018, I served the foregoing:

Via Federal Express and Certified U.S. Mail upon:
Hon. Jefferson B. Sessions
Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue N.W.
Washington, D.C. 20530

And Via Hand Delivery upon:
Hon. Benjamin C. Glassman
United States Attorney
Hon. William B. King II
Assistant United States Attorney
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202

Julie W. Popham

Julie W. Popham